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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,009	04/02/2002	Dario Alessi	002..00170	2823

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT PAPER NUMBER

1653

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,009

Applicant(s)

ALESSI ET AL.

Examiner

Maryam Monshipouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,12,23,52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,23,52 and 53 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>filed 11/05</u> . | 6) <input type="checkbox"/> Other: ____. |

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Applicant's responses filed 11/23/2005 and 5/31/2006 are acknowledged.

Applicant in response to species election requirement elected SEQ ID NO:25 and SEQ ID NO:30 without traverse.

Claims 2-3, 6-11, 13-22, 24-51 have been canceled. Claims 1, 4-5, 23 and newly presented claims 52-53 are still at issue and are present for examination.

Applicants' arguments filed on 11/23/05 and 5/31/06 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 12, 23, 52-53 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In traversal of rejection directed to the term "interacting polypeptide" applicant indicates that the specification provides examples of both "relatively small" and "other peptides" which operate as "interacting polypeptides".

Applicant further points out that possession may be shown in a variety of ways including a description of distinguishing identifying characteristics sufficient to show that the applicant was in possession of the invention. Here, the claimed invention is described in sufficient detail to allow one of ordinary skill in the art to recognize that applicant has possession of the claimed "interacting polypeptides" because they have the following two characteristics: (1) comprising SEQ ID NO:25 and (2) altering the substrate specificity of PDK1 and hence the rejection should be withdrawn.

These arguments were fully considered but were found unpersuasive. Firstly the examiner reviewed the specification pages indicated by applicant. More specifically, page 8 of the disclosure line 26, does not explain how much homology can be considered to be "substantially the same" and is only referring to preferred embodiments of "interacting polypeptides". The explanations provided in pages 10 and 11 once again provide some characteristics that interacting polypeptides may or may not possess. In page 10, line 27 the term "consist essentially of" is unclear and the length limitation of interacting polypeptide is indefinite. In page 11, again term "consist essentially of" is unclear and the equivalent regions of PRK1, PKB alpha, P70S6 kinase etc. to residue 960-984 of PRK2 are confusing. Therefore the examiner maintains that the species provided fail to represent the genus as broadly claimed and the characteristics which applicant considers to be sufficient for distinguishing the members of the genus indicated above remain insufficient due to lack of sufficient structural information about polypeptides species comprising SEQ ID NO:25.

In traversal of rejection directed to the genus of full-length PRK2 and PDK1 lack of structure in claims 1, 4, 5, 12, 23, 52 and 53 applicant argues that PDK1 and PRK2 have been both defined in the specification in pages 3-5. In addition the sequence of human PRK2, for example, is given in Figure 11 and therefore the rejection should be withdrawn.

These arguments were fully considered but were found **unpersuasive** because pages 3-5 of the disclosure merely discuss full-length PRK2 and PDK1 by function without even mentioning their sources or species. Further, Figure 11 merely defines the structure of human PRK2 (i.e. a **single species**) but applicant in claims 5, 52-53 has not recited the source of PRK2.

Therefore, currently both PDK1 and PRK2 are directed to a **genus** of polypeptides from all sources and species that lack adequate written description support.

Claims 1, 4 and 23 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of altering phosphorylation of human PDK1 of specific amino acid sequence with human PRK2 of specific amino acid sequence, does not reasonably provide enablement for methods of altering substrate specificity of PDK1 with an interacting polypeptide which comprises SEQ ID NO:25.

With respect to the term "interacting polypeptide" as discussed in the written description traversal arguments numerous species of the interacting polypeptides which include SEQ ID NO:25 are provided. Accordingly it would be well within the skill

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of the skilled artisan to determine the "interacting polypeptides" as claimed. These interacting polypeptides were shown to alter the substrate specificity of PDK1 (see disclosure page 45). It is well within the skill of one of skilled in the art to obtain interacting polypeptides which include SEQ ID NO:25 and to determine whether the polypeptide alters the substrate specificity. In page 48 of the disclosure even a simple test to determine if PDK1 substrate specificity is altered is provided. Therefore in view of applicant although some experimentation would be required such experimentation is not undue and therefore the enablement rejection should be provided.

These arguments were fully considered but again were found **unpersuasive**. With respect to traversal arguments provided in the written description section applicant is advised to kindly review the examiners' response provided above. With respect to applicant's additional arguments, he/she is reminded that the enablement rejection is not directed to the PDK1 substrate specificity determination but to the product to be used in such method. Applicant in both pages 45 and 48 of the disclosure is referring to the C-terminal region of PRK2 (also known as PIF fragment). The "interacting polypeptides" as recited in the claims need merely to comprise 6 residues of PRK2 and have no length limitation whatsoever. Therefore, even though applicant has provided ample examples of how to operate the claimed methods said methods are not enabled because of lack of sufficient guidance and examples provided for preparing the products used. For said reason the rejection is maintained.

Claims 4 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Said claims still recite the generic SEQ ID NO:30 and fail to recite the specific species elected. Applicant is reminded that the species claimed must be directly recited into at least one elected claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 5 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Meier et al. (EMBO J., 17(24), 7294-7303, 1998). Meier teaches that wild type HA-PKBalpha in HEK-293 transiently-transfected cells are activated by sorbitol (see page 7295 and figure 5). Meier also teaches that said activation is likely to be due to phosphorylation of Thr 308 and Ser473 residues of said PKB. Since phosphorylation and activation of PKB at residue Ser473 inherently occurs due to the exposure of PDK1 to PRK2 the method of Meier anticipates claims 5 and 53 of this invention.

No claims is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Maryam Monshipouri Ph.D.

Primary Examiner
